

REMARKS

Claims 1-15 are pending herein. Claim 16 has been cancelled without prejudice or disclaimer.

In the Office Action, the Examiner asked that withdrawn Claims 17-21 be cancelled. Since Claims 17-21 are subject to rejoinder, they are being maintained pending allowance of Claims 1-15. (See last paragraph, on page 2, of the Office Action of July 28, 2004.) For the reasons discussed below, Claims 1-15 are allowable. Accordingly, it is respectfully requested that Claims 17-21 be rejoined and allowed as well.

Claims 1-15 were rejected under 35 U.S.C. §102(b) as being anticipated by i) Thulé et al. (Diabetes, May 1999, supplement), ii) Thulé et al. (Abstract from Meeting June 9-13, 1999), and iii) Thulé et al. (Abstract from Meeting June, 1998) hereinafter “the Thulé publications”).

Independent Claim 9 is directed to an insulin regulator construct comprising a nucleotide sequence set forth in one of SEQ ID NOS: 3-6, and particularly to the elected species of SEQ ID NO: 5. It is respectfully submitted that none of the Thulé publications cited by the Examiner to reject Claims 1-15 under 35 U.S.C. §102(b) discloses the sequences of Claim 9. For this alone, it is respectfully submitted that Claim 1-15 are not anticipated by any of the Thulé publications. Accordingly, it is respectfully requested that the rejections of Claims 1-15 under 35 U.S.C. §102(b) over the Thulé publications be withdrawn.

In rejecting Claims 1-15 over the Thulé publications, the Examiner repeated his earlier comments and responded to the Applicant's arguments by stating that:

In response, it is respectfully pointed out that the Thule references relied on for the 102(b) rejections do teach adenoviral vectors that comprise all of the structural elements encompassed by the claims. Specifically the Thule references teach a vector comprising a GIRE of the L-PK gene promoter and an insulin sensitive element of the IGFBP-1 basal promoter wherein glucose increases the expression of a sequence operably linked to the construct and wherein insulin suppresses the expression of a sequence operably linked to the construct. Furthermore, the instant specification names the vector encompassed by the claims as Ad/(GIRE)₃BP-1 (e.g., see page 8 of the specification and the "Animals Studies" discloses on pages 53-54), which is the vector named in the Thule references.

Therefore, ABSENT EVIDENCE TO THE CONTRARY, the Ad/(GIRE)₃BP-1 2xfur vector that expresses the insulin transgene taught by the Thule references is the same Ad/(GIRE)₃BP-1 2xfur vector that is claimed in claims 1-15. (emphasis added).

As noted in the Amendment filed in the PTO on January 26, 2005, independent Claim 9 is directed to an insulin regulator construct and specifically recites a nucleotide sequence set forth in one of SEQ ID Nos. 3-6. As also noted in the same Amendment, none of the Thulé publications discloses the sequences of Claim 9. More particularly, while the Thulé publications generally discuss creating insulin transgenes or promoters for regulating insulin production, they do not disclose the specific sequences recited in Claim 9. Therefore, it is respectfully

submitted Claims 1-15 are neither anticipated by nor obvious over Thulé publications.

In the Office Action (Final Rejection), the Examiner stated that the vector named in the Thulé publications is the vector named in the instant specification and encompassed by the claims. Overall, the Examiner concluded that since the adenovirus vector, Ad/(GIRE)₃BP-1 2xfur that expresses the insulin transgene disclosed in the Thulé publications, has the same name as the vector disclosed in the specification, the vector recited in Claims 1-15 is the same as that disclosed in the Thulé publications. It is respectfully submitted that in so doing, the Examiner has used Applicant's own disclosure against him in rejecting the claims. It is well-settled law that an Applicant's own teaching cannot be used to support an obviousness or equivalency rejection. In re Kuehl, 475 F. 2d 658, 177 USPQ 250 (CCP A1973) and In re Lam, Cir. App. 01-1622, 2002 WL 962714 (Fed. Cir. May 9, 2002) (unpublished).

The Examiner further quoted the MPEP §2112.01 as stating that "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established.", and that "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not."

It is respectfully submitted that the Examiner, in the present instance, has concluded that the claimed invention and that which is disclosed in the Thulé publications are the same by erroneous relying on the Applicant's own disclosure. Further, as noted above, the Thulé publications do not disclose the specific sequences recited in independent Claim 9. The Examiner has not shown how one of ordinary skill in the art would arrive at the specifically claimed sequences from the Thulé publications, absent the Applicant's own disclosure. It is respectfully submitted that the Examiner's conclusion that the name of the vector in Thulé publications being the same as that disclosed in the present application renders the claimed invention anticipated or obvious is insufficient under the law.

In summary, Claims 1-15 are neither anticipated by nor obvious over the Thulé publications for not disclosing, teaching, or suggesting the specific sequences of independent Claim 9, and for the Examiner's improper reliance on the Applicant's own disclosure.

CONCLUSION

In view of the above, it is respectfully submitted that Claims 1-15 and 17-21 are neither anticipated by nor obvious over the Thulé publications. Withdrawal of all the rejections and allowance of these claims are earnestly solicited.

Appl. No.: 09/972,916
Amdt. After Final Rejection dated August 18, 2005
Reply to Office Action of April 20, 2005

It is believed that no additional fee is due for this submission. However, should that determination be incorrect, the Commissioner is hereby authorized to charge any deficiencies, or credit any overpayment, to our Deposit Account No. 01-0433, and notify the undersigned in due course.

Should the Examiner have any questions or wish to discuss further this matter, please contact the undersigned at the telephone number provided below.

Respectfully submitted,



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